Orthopedic Instrumentation Standardization

An Honors Thesis (HONR 499)

by

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Abstract

This thesis is to show the process, results, and industry and academic purpose of the Instrumentation Standardization Project (ISP) performed by a team of interns during the summer of 2016 at OrthoWorx, in collaboration with Zimmer Biomet, DePuy Synthes, and Paragon Medical. The ISP's focus was to provide savings to orthopedic companies through innovative and sustainable standardization of instruments that would allow the orthopedic industry to continue to advance and grow within Warsaw, IN. The results of the ISP showed that standardization of instruments was not only feasible, but beneficial as well, with an estimated 25 percent time-savings and 12 percent cost savings in manufacturing.

As a note to the reader, the three areas I led are discussed in detail (with the original project report as the appendix) to give the reader a fuller understanding of the project and my personal involvement. This was done to meet the academic requirements of Ball State University HONR 499.

Acknowledgements

I would like to thank Dr. Marilyn Chalupa for advising me through this thesis and providing clear and constructive guidance throughout classes and instruction during my time at Ball State University.

Thanks to Dr. Brad Anderson as this project allowed me to complete a double-major and a minor within four years, while also providing me with the proper education and support that allowed me to jump start my career and get a full-time job prior to graduation.

I would also like to thank the interns with whom the Instrumentation Standardization Project was performed, Ryan Cason, Prateek Kanodia, Jeremy Loss, and Noah Molter; our OrthoWorx facilitator, Laura Kernodle; and one of the most helpful consultants throughout the project, Mike Hawkins.

Also, thank you to Zimmer Biomet, Depuy Synthes, Paragon Medical, Orthopediatrics, and Medtronic for all the information and cooperation throughout the ISP and the time offered by many of their employees.

Lastly, I would like to extend the utmost gratitude to my parents, John and Brenda Perkey. They have encouraged, guided, and supported me my entire life. Thank you for your advice throughout the Instrumentation Standardization Process and this thesis.

Process Analysis

Throughout the project, research was approached with the intention of modeling current processes from the ground up to gain a complete understanding so that recommendations for improvements could be made. Data gathering was an integral part in the Instrument Standardization Project (ISP), so it was important to prepare properly and collaborate quickly after any data gathering was performed. Research preparation consisted of researching orthopedic terminology (see Appendix A, p. 22) and watching total knee arthroplasty (TKA) videos. Research was mainly conducted through interviewing individuals at the orthopedic companies in Warsaw, IN[1]. After each interview, the team would compile a document containing all our notes from the interview. Prompt compilation of information was crucial because it allowed us to collaborate and compare thoughts and ideas while the information was fresh in our minds. After every meeting, we had a brainstorming session to discuss the direction we should go with the new information gathered. This was done throughout the project, which allowed the project to be dynamic and change correspondingly with the information available.

The goal of the project was to develop a framework for instrument standardization used in TKA, and was expected to be achieved through thorough research of the orthopedic industry and orthopedic instruments, as well as proper use of information gathered from industry professionals. It was decided to prepare a framework of the current instrumentation value stream[2], introduce the opportunity of instrumentation standardization, and show the benefits of implementing standardization across certain non-proprietary instruments. Due to the constraint of ten weeks, the breadth of the project was narrowed down specifically to instruments used in TKA and then further narrowed to pins and screws.

The intended use of the project is that it will be used as an educational tool for the orthopedic industry and as groundwork for future intern teams at OrthoWorx. This is with the hope that the major industry players in Warsaw, IN (the orthopedic capital of the world) will implement our suggestions and eventually be leaders in instrumentation standardization so the rest of the industry will follow in their footsteps.

To conduct research throughout the project, the team and all companies involved were required to sign non-disclosure and non-compete agreements, which disallows release of specific company information. Some details about the project cannot be presented in this thesis; therefore, all findings presented in the project report (attached as Appendix A) have been stripped of all company-specific information to oblige the signed agreements.

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[1] All information presented in this thesis as well as throughout the ISP as a whole is intended to be specifically for the orthopedic companies with whom we worked (Zimmer Biomet, DePuy Synthes, and Paragon Medical), and should not be taken as generalizable information. Allowance was granted by the International Review Board (IRB) prior to any research conducted for this project.

[2] A value stream is the conceptual and physical path on which a product travels throughout its lifespan. In this project, the value stream is represented in a flow chart where each node is a process where value is added to the product.

Introduction

OrthoWorx is a third-party orthopedic consulting company that was founded from a Lilly grant in 2012 with the sole purpose to promote the advancement of the orthopedic industry in and around Warsaw, IN, so that orthopedics will remain centered in Indiana. The team of interns assembled for the Instrumentation Standardization Project (ISP) consisted of two engineering majors, one healthcare and policy management major, and two logistics majors (including myself). For the internship, we were tasked with developing a framework for instrument standardization used in total knee arthroplasty (TKA) to provide the orthopedic industry (specifically in Warsaw, IN, for this project) with overall cost and time savings, while also providing surgical staff with simplified instrument sets. Due to the complexity and novelty of the orthopedic industry to the team, research was approached with a ground-up mentality. We began with conducting research individually and meeting with industry professionals to gain a greater understanding of the industry. After basic information was understood, we decided on the instrument(s) we would standardize and finalized our research by collecting prints and information from the original equipment manufacturers (OEMs) and suppliers. Additionally, our research was solidified by participating in a Sawbones and cadaver lab (see Appendix A, p. 22).

To produce an understandable and educational presentation of our research, we compiled most of our information in the form of value streams and flow charts that showed the entire lifecycle of an orthopedic instrument. It was imperative that the results were educational because while the research was done primarily for the orthopedic companies in Warsaw, IN, a secondary goal was to provide a learning experience for those that do not understand the orthopedic industry. This was done to promote orthopedic education in Warsaw, IN, with the hope that more people would be encouraged to help grow the local industry.

The team concluded that there are not only benefits to standardization but that it is possible and an effective solution for the orthopedic industry. Some of the benefits that will be explained in detail later include cost savings and time reduction, increased safety, and reduced complexity within instrument sets. It also became evident that there were more opportunities for standardization than just within TKA instrument sets. From the foundation developed through this project, the team could show that instrument standardization can be applied to other orthopedic operations and instrument sets with similar results.

Methods

Throughout the project, the team utilized methods of gathering and presenting information that was provided by the previous team of interns. These methods included informal interviews, online searches, advisor meetings, and road-mapping sessions for collecting data. Our team also utilized online software such as Lucid Charts, Prezi, and Google Docs, and a report template provided by the previous intern team to present the information. Lucid Charts is an online tool used to produce flow charts; Prezi is a web-based PowerPoint-type service to create a dynamic presentation; and Google Docs is a file-sharing service provided by Google to collaboratively work on documents.

Although I was part of a team of interns for this project, we each had specific roles and focus areas. My areas of focus were the quotation stream; instrumentation standardization process; and business risks, dependencies, and mitigations. Each area involved extensive industry research.

Quotation Stream

After the instrument is designed and approved, the quotation process begins. For this to happen, there must be negotiations between the supplier and original equipment manufacturer (OEM). Through research of the quotation stream, the team discovered what was done and expected of both parties in preparation of manufacturing for each new or reengineered instrument.

For the quotation stream, I gathered front-end and back-end opinions of how the quotation process for an instrument takes place. Front-end opinions are those from the OEMs, whereas back-end opinions are from the suppliers. It was pertinent to have a thorough understanding of both opinions because both parties had their own preferences when it came to the level of involvement and stage of inclusion of the supplier. In most cases, the supplier wanted to be involved as early as possible, even in the design phase, but the OEMs generally preferred to keep the supplier(s) separate and provide them with little information until the quotation process had begun.

Much was learned throughout the research of the quotation stream. The complexity of the quotation process was unknown to me before this project. From prior work experience, I knew that before a payment is made, a quote is prepared to provide a tentative cost breakdown to the customer so the customer can compare the prices of multiple companies before purchasing the actual product or service. However, I did not know how many people were involved, the time it took for the entire quotation process, and the effect the quotation process had on standardization.

First, many more players are in the quotation process than the supplier and OEM. For the OEM, there are designers, engineers, marketing reps., and finance employees that take part in discussions with the suppliers from whom they wish to receive a quote. On the other hand, there are engineers, purchasing agents, and manufacturing supervisors that represent the supplier during negotiations.

Second, the quotation process can take anywhere from a couple days to months. The duration of the quote phase is dependent on the complexity of the design, the feasibility for the supplier to complete the project, whether it is a new product request, and the quality constraints enforced by the OEM. For instance, if the production of a part would be too expensive for the supplier to take on the project or the supplier does not have the appropriate storage space or machinery to complete the project, the project would be unfeasible and a "no quote" would be issued for that project. Also, if the product makes it through the budgetary quote phase (the project was deemed feasible by the supplier), it would advance to sample production. If it did not meet the quality requirements of the OEM, they would re-enter negotiations on design and start the quotation process again.

Lastly, I discovered the importance of the quotation process within the Instrumentation Standardization Project (ISP). No matter the design of a standardized instrument or any agreement between companies to use a standard instrument, nothing can happen unless the product is feasible for the supplier. Another major issue involved with standardization is what

party will hold the design rights[3]. If an OEM holds the rights, they could get sued for a fault in the standard product in a competitor's knee system. Likewise, if a supplier holds the design rights, they would be the only supplier that could produce the standardized instrument, which would hinder fair competition practices. Therefore, an exception or agreement must be made specifically for standardized instruments for standardization to be successful.

Instrumentation Standardization Process

The process of deciding what instrument to attempt to standardize proved more complicated than expected. The team had originally set out to standardize a cut-block[4], but after discovering the proprietary rights involved in an instrument with such detail, it was decided to do a simpler instrument to show proof-of-concept. The instrument set decided on was pins and screws, from which we performed extensive research both within and surrounding the orthopedic industry.

Standardization among instruments used in Total Knee Arthroplasty (TKA) has never been attempted (at least there are no documented accounts of it occurring at the time of this study), so the task appeared quite daunting at first; however, the team was not entirely pioneering. Research indicated that there has been standardization, specifically with surgical instruments in other areas in the medical industry but not in orthopedics. The benefits found from standardizing surgical instruments through a study done at Seattle Children's Hospital were complementary to the findings of our study, which will be discussed later (Avansino). Initially it was assumed that choosing to standardize only pins and screws was too small of an area to focus, but it was the only feasible direction given the scope of the internship. Instruments as small as pins and screws can have an impact on more than just the bottom line. Other studies that will be discussed later were encouraging because they demonstrated actual evidence of standardization both reducing complexity of the supply chain and reducing risk of accidents during surgery – both of which are good.

Through researching instrument standardization possibilities, it became evident that there were some restrictions due to the classification of certain instruments, which was the main reason why we could not pursue cut blocks for standardization. Cut blocks are a Class II instrument, whereas pins and screws are Class I. Further explanation can be found under the Regulatory Stream on page 6 in Appendix A, where it states,

> As a general rule, if an instrument covers the description of two different product codes it is not considered device-specific. Device-specific instruments result in non-invasive, Class I legacy instruments taking a Class II classification. Typically, Class II instruments require more testing and data collection than Class I devices as they are considered of higher importance to the quality of the surgery.

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[3] Design rights specify what company is responsible for the design of the product so that if there is an incident with a part breaking, the holder of the design rights is the legal owner of the product.

[4] A cut block is a guide used in orthopedic surgeries to properly direct the angle of the saw blade when cutting away bone.

Due to the classification constraints imposed on the instruments, the number of feasible instruments to standardize was limited. The team decided that the research for standardization of pins and screws would be useful because it provides a framework for future implementation. Also, a forward-thinking focus was intended with our suggestions for standardization, meaning that standardization of instruments would be used with future knee replacement systems rather than trying to incorporate the new designs with predicate systems.

Business Risks, Dependencies, and Mitigations

The purpose of defining business risks and mitigations was due to credibility. The team knew that for the companies to trust our work, we had to show that we had thought of everything. While the engineers in the group continued to analyze the details of a standard pin and screw, I used business and industry knowledge learned through education and the internship to spell out the risks of standardization and how to avoid and/or minimize the adverse effects of such negative possibilities. I also researched the dependencies of standardization, which defined what information must be available and certain changes that must be made to make standardization viable in the future.

Speaking with industry professionals, general industry research was conducted to find what concerns standardization might raise for the companies involved as well as what is necessary for standardization to be successful. As can be seen in the report, some of the main risks that were found were due to intellectual property (IP)[5] inertia and the effects on instruments other than the one(s) standardized – pins and screws in this case (Appendix A, *Business Risks*). The issue with IP inertia is that companies do not want to give up anything that is rightfully theirs, but when the benefits of standardization are considered, it is ideal for companies to set aside their differences and work together for the betterment and sustainability of the industry.

However, it can be difficult for competitors to work together in fear that they might expose themselves too much, which could result in the loss of IP. Because of this, the solution proposed for this risk is to utilize a third-party company (such as OrthoWorx where this project was done) to keep all confidential information out of the hands of competitors while it can be compared with industry norms to find commonalities that can be standardized. Additionally, while standardization of a single instrument had proved to be challenging, another complication happened when introducing the standardized instrument. The issue was that even if a small instrument such as a pin or screw is standardized, then that means that all instruments that interact with the pin or screw must be altered to accommodate the new standardized features. Additionally, for standardization to be successful, companies must make all relevant information available to those analyzing the information to find opportunity for standardization.

This process showed that instrumentation standardization is not only possible, but that it has little risk when done for simpler Class I instruments. Also, when the potential benefits are considered, which will be discussed later, standardization seems to be an essential next step for the orthopedic industry. However, as was just addressed, there must be either complete collaboration

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[5] For all intents and purposes, and to remain consistent with the project report, IP is "anything considered confidential by a company" (Appendix A, p. 22).

between companies or wholesome trust in a third-party company as well as transparency of information to foster and expedite the standardization process.

Results

The project resulted in 25 percent time savings and 12 percent cost savings for each pin/screw that would be produced as a standardized product. While the detailed savings cannot be disclosed due to the non-disclosure agreement, the savings are considerably substantial, which should at least warrant some interest from the OEMs and supplier with whom we dealt and possibly the entire industry. The team also discovered more benefits from standardization, such as higher economies of scale, greater manufacturing efficiency, better forecasting accuracy, and more, which can all be seen in greater detail in the project report (see Appendix A, p. 19).

Discussion

The team learned quickly that being as informed as possible before speaking with an industry advisor was far more effective than having a remedial understanding and expecting to learn throughout the meeting. Conversations with advisors were helpful, but having a broader knowledge of the industry and topic at hand prior to meeting enabled us to gain a deeper understanding and build on our knowledge, which would eventually earn us credibility among industry leaders. With the credibility, those with whom we met felt more comfortable sharing information with us, which allowed us to gather more data than we initially thought possible.

Although there were no studies found for instrumentation standardization within orthopedics, our research and findings are not without validation; multiple studies show the benefits of standardization with surgical instruments, and most of the outcomes of these studies are similar to ours. As mentioned previously, there was a study done at the Seattle Children's Hospital that was focused on standardization of surgical equipment for laparoscopic appendectomies with the hope of finding a way to reduce surgical costs safely. They found an average of 20 percent savings per case in supply costs (Avansino). When that is compared to our results, it is possible that the cost and time reduction in production can be passed down to the cost per case, which would provide the savings for the end-user as seen in Avansino's research.

Further support comes in an article from Aesculap that spells out the benefits of instrument standardization and the resulting simplified supply chain. They list three main benefits, reduced complexity, accurate inventory, and increased utilization (Instrument Standardization). These benefits were also seen in our results as additional benefits to the time and cost savings.

Finally, an interview with Rosemary King conducted at the Virginia Mason Institute revealed possibly the most urgent reason for standardization to be adopted: prevention of adverse events with patients. While this article deals mostly with reduction of variation regarding surgical instruments in the operating room, the principle of standardization still applies to our findings. Standardization provides more than just cost benefits, which is realized in the reduction of complexity and volume. When there are fewer instruments used in a surgery, there are inherently fewer mistakes made when selecting the correct instrument and it simplifies the process, which could even save operating time in the long run.

Conclusion

Throughout the project, it was imperative that every member completely understood their respective areas. While my focus was primarily on the quotation stream; instrumentation standardization process; and business risks, dependencies, and mitigations; every area of the project was of equal importance. The results from the ISP could greatly impact the companies with whom we worked, the industry, and academia. If implemented, Zimmer-Biomet, DePuy Synthes, and others from the area could benefit from the monetary savings and marketing simplicity. The industry would hopefully follow suit and adopt instrument standardization, making orthopedic surgeries more cost effective and streamlined. Regardless of implementation, the findings can be used in various academia to inform students in Warsaw and across Indiana of the importance and possibilities of advancement in the orthopedic industry. OrthoWorx also intends to use the research from the ISP as a platform for future intern teams to further advance standardization research in the orthopedic industry.

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Instrumentation Standardization Project Written Report

Ryan Cason, Prateek Kanodia, Jeremy Loss, Noah Molter, Tim Perkey

August 4, 2016

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Introduction to Project and Scope

Total Knee Replacement System Background

A total knee replacement consists of 4 component parts: the femoral component, tibial plate, polyethylene bearing, and polyethylene patella (see Figure 1). The femoral component is implanted on the distal femur (bottom of thigh bone) and replicates the anatomy of the natural femoral condyles. The tibial plate is mounted to the proximal tibia (top of shin bone) to replace the tibial plateau and provide a base for the polyethylene bearing. The polyethylene bearing sits atop the tibial plate and provides cushion and a smooth pivot surface for the knee replicating the anatomical menisci. The polyethylene patella replicates the natural patella (knee cap) by providing a smooth sliding surface against the femoral component. All of these base components require a complete line of different sizes as well as accompanying trials for each size.

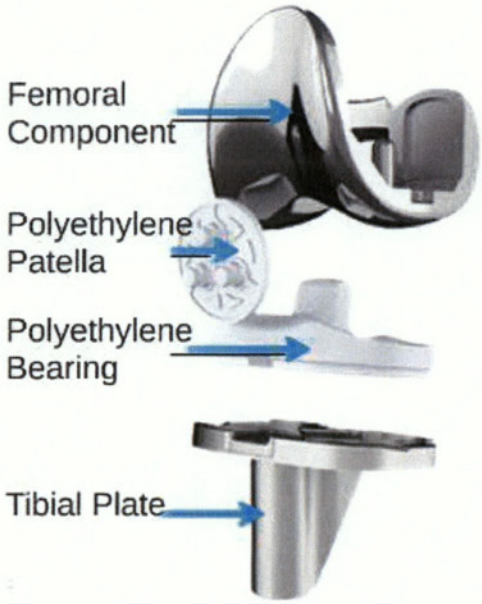


Figure 1: Total knee replacement components

Instrumentation Overview

Currently, a total knee replacement procedure can require over 400 different instruments for preparation and installation of different components of the arthroplastic implants. Instrumentation in the orthopedic industry is unique because it is considered capital by the company and therefore returns no reimbursement from its production. Although every total knee replacement system across the industry follows a nearly identical surgical process and consequently uses very similar instrumentation, there is little to no standardization of instruments across systems. Not only between companies are there no universally applicable instruments but also within companies there are incompatibilities between different design divisions' instrumentation and between different implant systems from the same division. During an operation there can be between eight and twelve instrument sets present on the back table produced by the

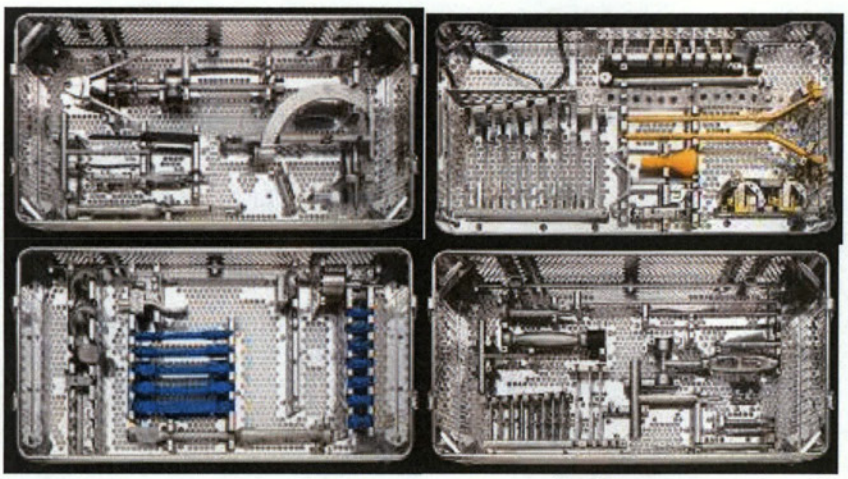


Figure 2: Instrument cases and trays, courtesy of Zimmer Biomet

OEMs. The hospital may also provide additional general surgical instruments for the surgery.

Project Scope

The aims of this Instrumentation Standardization Project were to gather data on instrumentation and create a representative value stream for the industry in its current state, analyze opportunities for value stream optimization, and investigate the feasibility and cost savings of standardized instruments. As a final product, we have created a process for standardization of instruments in the orthopedic industry and using that process with an example product. Completion of this effort required over 60 hours of interviews and meetings within the group's nine-week timeframe with individuals of diverse orthopedic industry experience, education backgrounds, and perspectives.

After interviews, data gathering, and deliberation, the project focus was directed towards the standardization of pins and screws used in total knee replacement procedures. Pins and screws are some of the least intrusive instruments to change contained within the set; as to say, changing pins and screws would create the least amount of interference with parts of current systems that are associated with pins and screws. Therefore, the focus of pins and screws was believed to be an appropriate target for the group's time frame of a nine-week internship. This proof of concept for standardization of pins can be extrapolated then to more complex instruments in the future like pin pullers, drivers, or handles for examples.

Value Streams

A value stream is a lean business method to visually map the current supply chain from product initiation to delivery or service and its use by the customer. This shows the flow of how a company operates to provide a customer their product and how that product is used by the customer. From this model, a company can make changes to increase their efficiency in areas to increase productivity and reduce costs. This differs from a supply chain one might be used to seeing because it includes the customer end-use and manufacturing of the product, whereas the supply chain only maps how a product order fulfillment takes place.

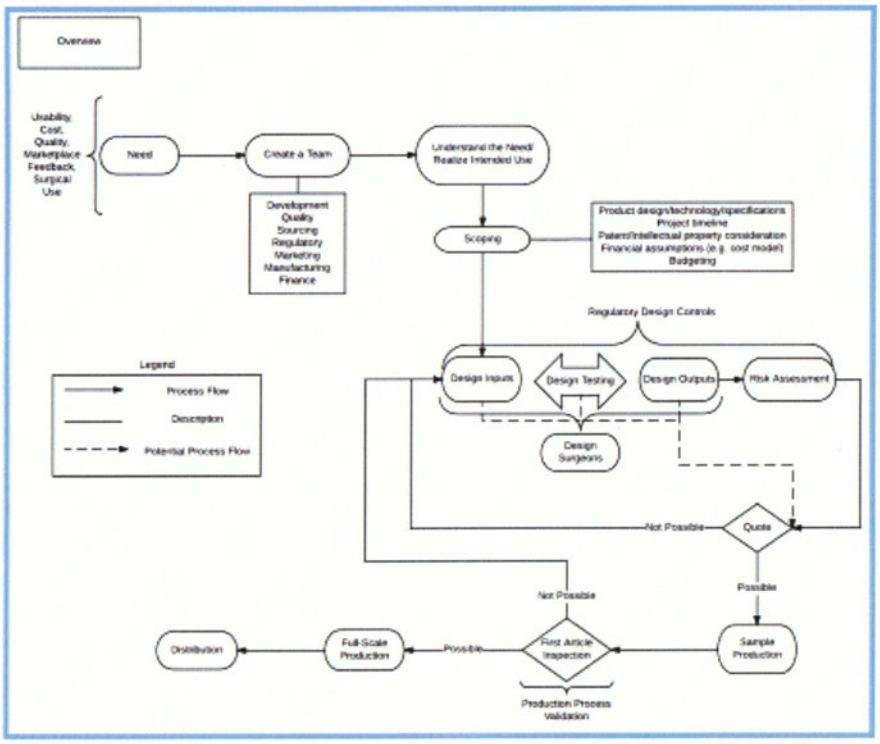


Figure 3: Instrumentation
Value Stream

Design Stream

The value stream for a new instrument begins with a need that can be driven by a multitude of factors: usability, cost savings, quality, and surgeon preference. Feedback on these factors comes to the company through focus group meetings with design surgeons, suggestions from hospital surgeons through the sales representatives, product failure reports, and other sources. When a need is brought to an OEM, a design team is formed to understand the need and properly address the issue caused by the need. The design team typically consists of company employees spanning the development, quality, sourcing, regulatory, marketing, manufacturing, and finance departments. Each member of the design team manages a different aspect of the design process based on his or her specific department. The first item the design team is tasked with is to understand the need brought to them. For a new instrument, this would include reviewing collected information and translating feedback into quantifiable features. At the end of this process, the design team would agree upon an instrument that contains the determined quantifiable features.

Following the inception of the needed instrument, the design team would then move into the scoping phase of the value stream. In this phase, the design team determines the parameters that they will be working within for this project. Specifically, the team will determine a project timeline with checkup meetings to determine the progress of each member department, and to make sure the team is moving swiftly towards the determined finish date. The team, and more

specifically the finance department, will also determine the project budget to determine the size of the capital investment the company will put into the project. Along with that, how the company will handle the intellectual property created for this project has to be discussed with the team and the company's patent office. In addition to setting the project parameters, the scoping phase also includes creation of preliminary cost models of the instrument to estimate the costs and other financial additions associated with production of this instrument. Along with the cost models, the sourcing and manufacturing members of the team would analyze the manufacturing capacity of the company and determine if the OEM will make the instruments in-house or buy the instruments from a supplier. Finally, the development, quality, and manufacturing members of the team will begin fleshing out the specifications of the instrument in greater detail at the end of the scoping phase as the team moves into design inputs.

Once the project scope has been finalized, the value stream moves into the design segment. During this time in the value stream, the development, quality, and manufacturing engineers begin defining the specific features necessary for the instrument to meet the need. Quantifiable, measurable, and unambiguous values, such as dimensions and materials, are determined as design inputs through clinical feedback and research. As these values are defined, prototypes of the instruments are built and the quality engineers test these instruments for biocompatibility, cleanliness, ease of sterility, strength, toxicity, MRI compatibility, and other aspects necessary to the medical field. Design surgeons are also brought in to offer feedback on the prototypes to determine how well the current product meets the needs in the marketplace. Class II instruments and higher surgical preference Class I instruments are the focus of these design surgeon meetings rather than lower surgical preference Class I instruments. Throughout the design segment, the engineers working on the product maintain careful notes on what processes are used and are to be used on the product to adhere to the company's quality assurance standards. It is the quality engineers' job to assure that all the work being done is well documented and follows the FDA guidelines. Quality engineers also focus on the risks that come along with the new instrument, such as if it breaks during surgery or if it not used for its intended use. Risk assessment is constant throughout the design process, but it is also conducted on the finalized product right before moving into the quoting phase. Once the instrument features are solidified, final CAD drawings, models, Critical to Quality features (CTQs), along with final prototypes, are produced and prepared to be sent to the production floor, whether that be in-house or to an outside supplier.

Regulatory Stream

Regulatory affairs are growing departments of OEMs as regulations grow stricter and globally more diverse. Regulatory bodies are requiring more information and data to prove the safety and effectiveness of instruments and lack consistency in their internal reviews and across borders. The regulatory team ensures proper documentation of quantifiable data that is imperative to device clearance and potential audits.

Instrument classification is a key component to the regulatory process. In 1976 the FDA released the Federal Food, Drug, and Cosmetic Act, which regulated medical devices and created class I, II, or III devices. Class I devices do not require premarket approval and are non-invasive instruments that can be used across knee systems. Class II devices require a 510(k) clearance, which is a premarket notification that allows the FDA to determine if a new device is equivalent to a predicate device. Instruments that are classified internally as class II must register to notify FDA at least 90 days before their expected date to reach market. Class III devices require

premarket approval (PMA) and clinical trials for clearance. Class III medical devices are beyond the scope of this project as they are not included in the knee systems examined. All instruments correspond to a 3 letter product code which is assigned based upon the medical device product classification designated in 21 CFR Parts 862-892. The product code that the device falls under will determine the classification of the instrument.

It is important for the regulatory affairs teams to stay up to date on FDA guidance documents. Guidance documents provide insight on the agency's current thinking on a particular topic and provide recommendations for design and manufacturing processes, content of submissions, and quality inspection policies. The guidance documents are not to be considered the law and can be modified at any moment. By keeping up to date with guidance documents, the submission will be more complete which could result in a faster time to clearance. A more complete submission will include data that is focused around the current issues identified and prioritized by the FDA. Regulatory teams must also stay up to date on international standards such as ISO and ASTM standards. Regulators use a variety of standards as their guidance and it is important that these are identified and followed to ensure clearance.

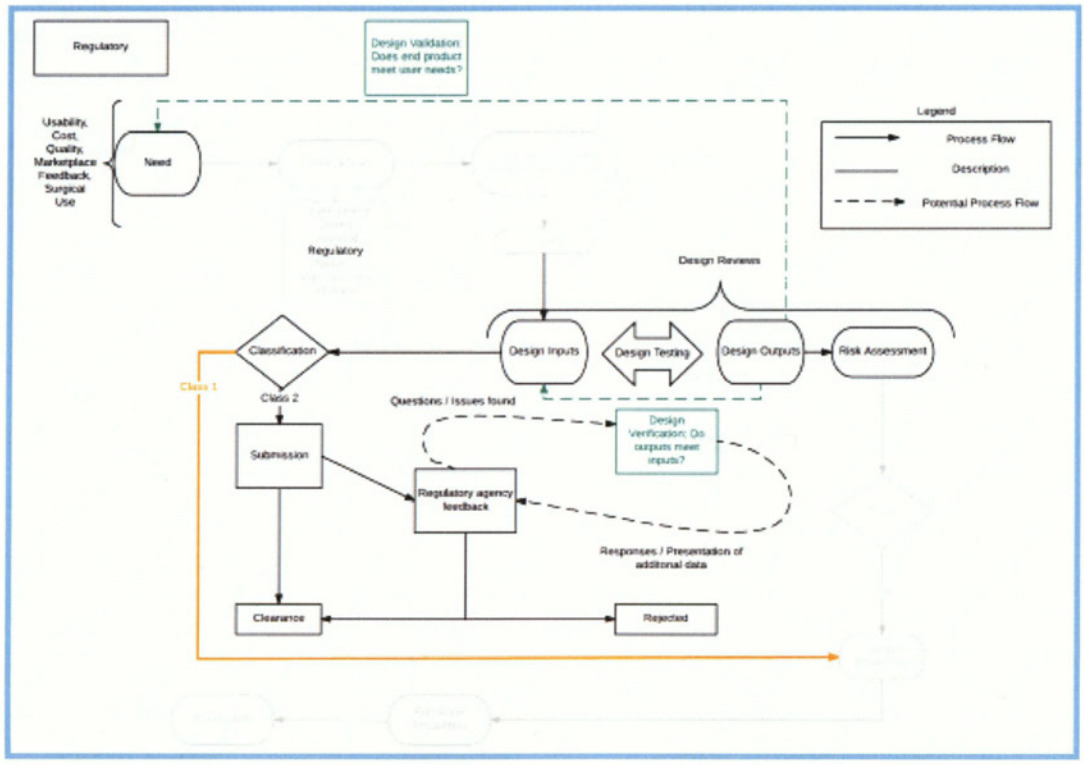


Figure 4: Regulatory Value Stream

Device-specific instruments have caused confusion and a lack of clarity between regulatory affairs teams and regulators. These instruments can only function with one knee system and they take the classification and product code of the implant. Classification is complicated when instrument sets are specifically named for an implant but can be used across systems. The instrument's classification puts more influence on the functionality of the product rather than its' naming. As a general rule, if an instrument covers the description of two different product codes it is not considered device-specific. Device-specific instruments result in non-invasive, class I legacy instruments taking a class II classification. Typically, class II instruments

require more testing and data collection than class I devices as they are considered of higher importance to the quality of the surgery. Quality engineers are spending more time on instruments that traditionally required less measures for design verification. Throughout the design processes the regulatory team works with the design and quality engineers to ensure proper documentation and data collection on critical to quality key indicators to achieve clearance from the regulatory agency.

As stated earlier, Class II devices must apply for 510(k) clearance at least 90 days before expected marketing launch date. A 510(k) submission has the goal to prove equivalence to a predicate device. Information that the FDA wants to be included in the submission can be found in the guidance documents of the predicate device. When dealing with a non-device-specific class II device, the submission will include safety and effectiveness measures and also proof of parallel functionality to the predicate device. Device-specific instruments are included in the submission for the knee implant. The bulk of the implant will be focused on the implant itself. The device-specific implants will be listed in the submission, but data will not be provided for each instrument listed. Data regarding safety and effectiveness will only be included for instruments the company forecasts the regulatory agency will desire critical to quality data for to allow clearance. Submissions are most likely to include biocompatibility and coloring information. Although quality control data may not need to be presented in the submissions, the company keeps internal documentation of this data. This data will be needed in the possibility of an audit or if a specific instrument receives an overwhelming number of complaints. Internal documentation includes Design History Files (DHF) and the Device Master Record (DMR). The DHF is the ultimate record proving the satisfaction of design controls. It needs to be traceable and organized to show the linkages and relationships between design controls and CTQs. The DHF can be audited at any time by regulators and is the main document investigated. Design controls and recommendations for design and development planning, input, output, review, verification, validation, transfer changes and the design history file can be found in 21 CFR 820.30. This code of federal regulations outlines the documentation for the processes listed.

After submission, the regulatory body will issue a device either clearance or a refusal to accept (RTA). If clearance is granted, the device is deemed safe and effective and has functional equivalence to a predicate device. A RTA can either be an interactive process or a listing of information that restricted the initial submission from clearance. If the OEM has data to alleviate the problems indicated by the RTA they can provide the data asked of them for resubmission. The device will be cleared if the agency's questions are answered. If the problems cannot be answered with quantifiable data, the submission will be rejected and the device will not be cleared for the market. A resubmission is not required but it is imperative to internally document these changes if minor design changes are made. If a change affects the safety and functionality of the device, then a resubmission is required. Depending upon the location, device tracking may be necessary. The USA does not require device tracking and relies upon complaints to identify risk in devices. Outside of the United States, regulatory teams must continue to collect data on device usage and performance.

The goal of global regulators is to ensure public safety to the best of their ability. Different countries have different quality control recommendations, classification practices, and requirement for submissions. OEMs that bring their products to the global market must obtain clearance in each separate market. The result is complexity and burden for the regulatory affairs departments. The different markets place emphasis on different aspects of the process. Submissions must be tailored to fit the mindset of the country in question. A submission that is

cleared in one country is sure to raise questions in another. It is up to the regulatory team to identify additional data and changes that need to be made to the submission. It is also a possibility that a device that does not require a submission in one market may be take on a different classification that requires a submission in another. Markets have different timelines and regulatory processes that add burden to gaining market clearance.

Quotation Stream

In the quotation stream (fig. 5), the first thing that must happen is for the OEM to submit a request for quotation (RFQ) to the supplier(s), such as an entity like Paragon Medical, from whom they wish to receive a quote. The RFQ contains prints and quantities of the desired parts that are to be quoted. The amount of information provided differs between and within companies depending on what is being produced; however, solid models are rarely given to suppliers at this time despite the ability to provide more accurate quotes if the models are available. One reason for OEMs to not provide solid models with an RFQ is because of the expense of producing the models when there may be changes in the design later in the design and quotation process. After the prints are received, the supplier performs an opportunity assessment in order to ensure their capability to perform the requested task(s). If the request appears feasible, they then move forward into the budgetary quotation phase.

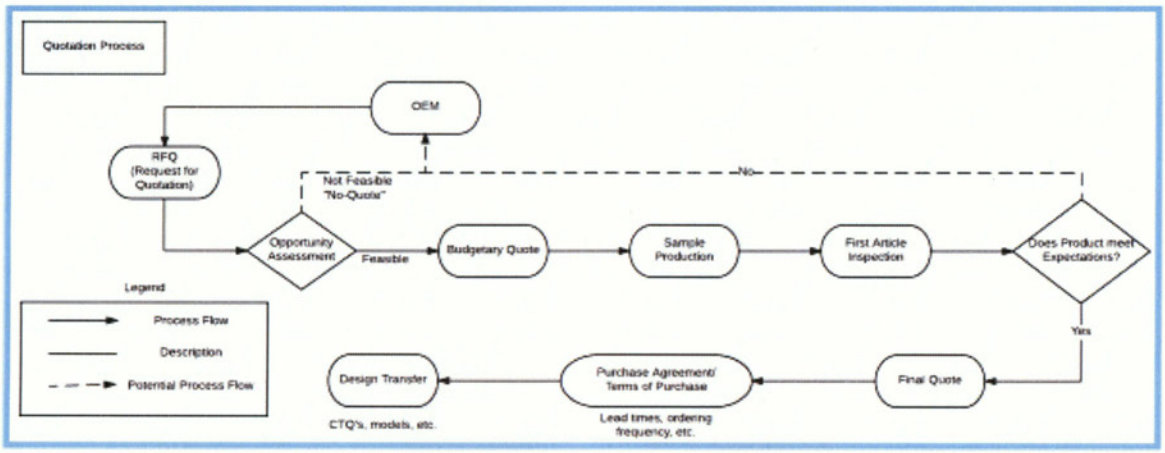


Figure 5: Quotation Value Stream

A supplier prepares a budgetary quote with part numbers, quantities to be produced, lead time(s), price, and any disclaimers. A proposal is prepared for larger projects that require a significant amount of non-recurring engineering (NRE) activities. In the case of a proposal, a refined timeline and detail of NRE expenses are included.

After a budgetary quote is prepared, the supplier moves into sample production. In sample production, the supplier produces a small number of samples on the manufacturing floor in order to ensure capability of holding all tolerances and performance specifications. Immediately following sample production is first article inspection. First article inspection is a quality check performed by the OEM to confirm that the product meets expectations. The supplier provides a final quote once the OEM accepts the product. In a final quote, prices are updated based on the supplier's capabilities and any design for manufacturing (DFM) costs that

have been incurred to this point. The supplier then discusses the terms of purchase in a purchase agreement which further specifies lead times, ordering frequency, and so on. Subsequently, after the job is awarded to the supplier, they move forward into design transfer. Included within the design transfer are prints, quantities to be quoted, solid models, CTQs designated by the OEM, and updated designs based on supplier capabilities (if applicable).

Production Stream

Concerning pins, OEMs nearly always outsource the manufacturing to a third party supplier. The factors that comprise this purchase-over-make decision are largely equipment capital and labor costs. Instrument sets currently require over four hundred instruments and many of those instruments are assemblies of multiple smaller parts. This creates a need for a large scale manufacturing floor with a fleet of manufacturing and inspection machines that cost upwards of a half million dollars per machine. That initial equipment cost in conjunction with the cost of laborers to program, operate, and maintain them pushes OEMs to outsource production to designated orthopedic suppliers.

The initial production stage begins once the quotation phase takes place with the OEM and supplier. Engineers and programmers from the supplier work closely together to translate

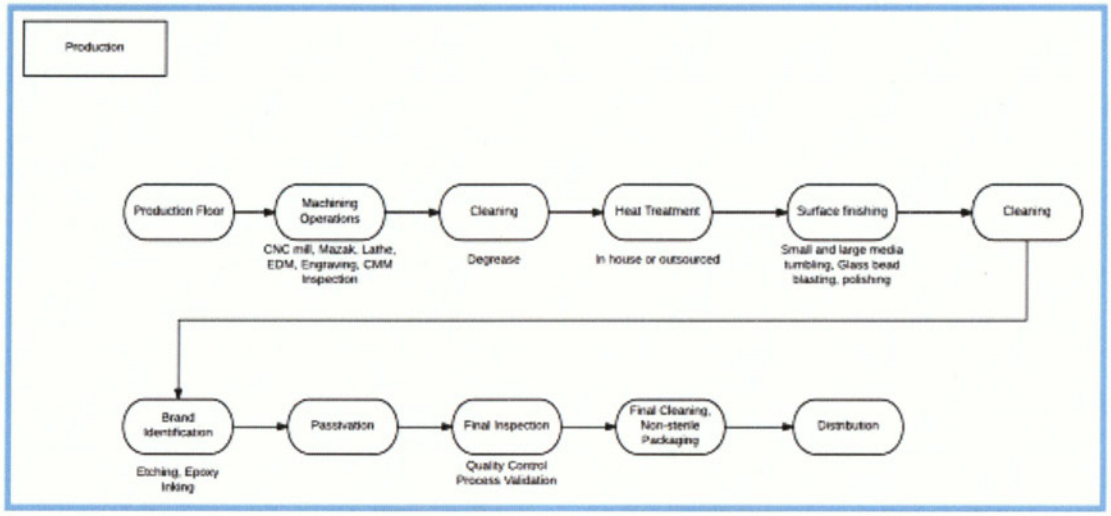


Figure 6: Production Value Stream

prints into the most efficient machining codes and inspection methods for the machines on their floor. The sample production run then takes place on the manufacturing floor. All machining operations that will take place in the full-scale production are used to validate the manufacturing process to the OEMs. This would include any of the following primary machining operations and some specialty operations possibly not listed: CNC, Mazak, lathe, Wire EDM, engraving, and CMM inspection. After all primary machining is completed the part is sent through a cleaning process, which is a degreasing at this point to remove machining lubrication fluid. Due to history with cleanability, suppliers clean parts regularly between operations to ensure any particulates are removed and won't cause problems later for the patient. The part is then heat treated to harden the material and remove plastic deformities received during the machining process. This heat treatment can be in-house or outsourced based upon the availability of a furnace on site at the supplier. Secondary processes take place after heat treatment and are very important to the OEM due to the marketing and sterilization implications of the surface finishing. Surface

finishing processes never take place after heat treatment due to the harder material, which would be slower and more expensive. Small and large media tumbling, glass bead blasting, and polishing are a few examples used in the surface finishing stage. The parts are cleaned again and then sent for brand identification. This stage includes etching and/or epoxy inking to have required markings and brand markings on the instrument. These markings could be item numbers, logos, CE markings, etc. Both surface finishing and brand identification stages can have a wide range of variance due to wear considerations as well as purely aesthetic concerns. The specimens then go through a passivation, or upgrading, process where the material is given a treatment to prevent chemical reactivity and therefore reduce corrosion. A final inspection is then conducted for the part where quality engineers are heavily involved to ensure the production is within the specifications. The parts go through a final cleaning and are non-sterile packed and shipped to their necessary locations.

Standardization of instrumentation has large cost-saving implications. Manufacturing processes can be explained on a spectrum of efficiencies based upon the products being fabricated. On one end of the spectrum are custom-made products where there is low volume and high variability. That, in turn, makes manufacturing slow and expensive for the customer. Inversely on the spectrum is the standard product manufacturing that is fast and more economical when volume is high and variability is low. In manufacturing, high volume and low variability is optimal for the lowest costs because of the opportunity for designated machines; there are time efficiencies gained with designated machines due to no instrument changeover, changing setup for a different instrument, which therefore lowers cycle times. Although these costs saving may seem insignificant under a magnifying lens, the savings quickly amount when volumes increase with a now standard instrument.

An area of optimization in the supply chain that can reduce labor and something that the FDA is currently pushing is to use statistical process control (SPC). SPC gathers numerical data from the inspection of products and plots it with the control limits therefore providing an accept/reject analysis that also includes quantifiable reasoning. This data can also assess the efficiency of the process and determine whether the products are within the control limits in a consistent fashion or the process is unreliable and has large deviations. This also provides quantifiable data to validate a machining process. The advantages of using SPC is that it shows numerically exactly where products are being manufactured within or outside of the limits and then can be more precisely adjusted to be within those specifications. Inspection processes like go/no-go gages cannot give this data due to their limited result output of approved or rejected and cannot produce reasoning for either result quantifiably.

Distribution Stream

The supplier manufactures instruments and ships the product to the OEM's distribution center. The OEM's distribution center keeps all of the implant and instrument inventory. Once the OEM physically receives the instruments, they record it in their system. This step adds the received shipment to the inventory of the OEM's instruments.

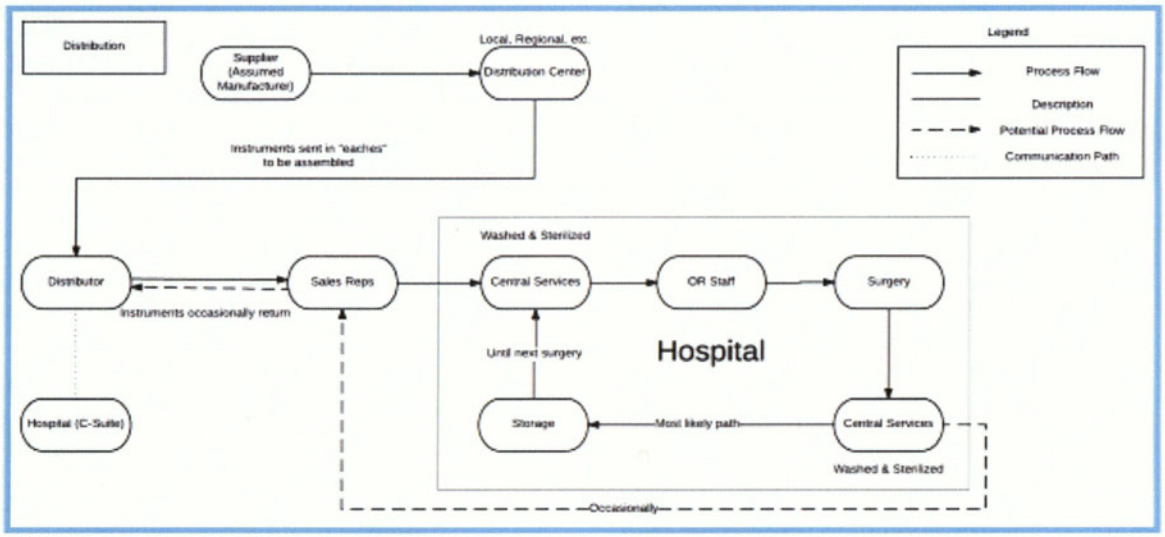


Figure 7: Distribution Value Stream

Based on demand for instruments from customers, the distributor places an order with the OEM. The distributor is an independent entrepreneur who has an agreement with the OEM to sell their products. Instruments are consigned to the distributor to allow them to service their customers; however, title remains with the OEM. Once the demand is validated with distribution planning and inventory is allocated, the OEM ships the instruments out from the distribution center to the distributor's warehouse. Each instrument and the instrument case is packaged separately. The distributor unpacks all instruments and assembles an instrument case at their warehouse.

At all times, the ownership of the instruments remains with the OEMs. They treat it as inventory. From an accounting perspective, the instruments are held as inventory and do not calculate depreciation costs until they are shipped out to the distributor. Once they are, the OEM depreciates them as per company policy. However, in reality, the instruments have a longer useful life and are still in the field being productive. The sales representatives are responsible for supplying the instrument cases to hospitals and surgeons (along with the implants). They accompany the instruments (for the most part) while the instrument set is in the field.

When the instruments reach the hospital, they sent to Central Services for sterilization and sterile-wrapping. After the instruments are cleaned, they are wheeled into surgery. At all times, the instruments remain sterile-packed until the OR staff unpacks them in the sterile zone within the operating theatre. The staff assembles the instruments as required during surgery before handing them to the surgeon who performs the surgery. The sales rep usually remains in the surgery room to guide the OR staff or the surgeon to correctly assemble and use the instrument during surgery. After the surgery is completed, the used instruments are sent back to the Central Services where they are disassembled, cleaned, and sterilized again. The sales reps

along with the staff reassemble the cases before the instrument case returns with the sales rep to the distributor. If the relevant surgery is performed often in that hospital, the instrument kit may remain in the hospital.

Our biggest takeaway from this value stream was that multiple sets of people handle the instruments in different capacities throughout one cycle. The distributor assembles the instrument case, Central Services staff disassembles and cleans the instruments, the OR staff assembles them for surgery and the surgeon operates with them. The instruments need to be easy and intuitive to work with, for everyone. Second, the distributors are liable for the instruments beyond normal wear-and-tear. If the instruments are damaged while with the distributor, the OEM seeks a cost reimbursement from them. The distributor may seek reimbursement from their customer in turn, if they damaged the instrument. The distributor also undergoes an annual stock audit, where the book-stock (instrument inventory as per OEM system) and the physical instrument inventory at the distributor need to match. Third, achieving service quality is considered the unequivocal primary goal. All parts of the value chain are strongly oriented towards meeting customer needs in the 'moment of truth'. Any failure in an instrument providing the right level of service can put the surgery in jeopardy and destroy a relationship with a customer that was built over many years.

Value Stream Optimization

After the value stream had been properly mapped out, the team looked for areas within the value stream to optimize for greater overall efficiency. The group identified the following as possible opportunities for future intern teams to research. The first area for optimization was a base information requirement for the OEM before meeting with the supplier. Currently, an OEM can come to a supplier with varying amounts of information and it is up to the supplier to form an initial budgetary quote with this given information. The accuracy of a quote ranges based on the quantity of information received, which slows down the quotation process. If prints, models, CTQs, production volumes and lead times were all necessary before the initial meeting with a supplier, the initial budgetary quote from the supplier would be more accuracy and the overall quotation process would be streamlined.

Another area for optimization the team found in the value stream would be creating a standardized guideline for datum referencing when designing new instruments. A datum is simply a reference point on a Computer-Aided Design (CAD) model. Currently, designers have free range when determining how new instruments are referenced. For example, one designer may reference all of a pin's dimensions off of the head of a pin while another designer may reference all dimensions off of a plane that dissects the pin and a third designer references all of the pin's dimensions off of a central axis through the pin. Because of these different referencing styles, a supplier has to reconfigure how the raw material is fixed in their machines as well as how their machines reference the material for each of the three pins. If, however, the guideline for datum referencing specified that all pin dimensions were to be referenced off of a pin's head, suppliers would have to do significantly less reconfiguring on their machines to produce all three pins. This example is just one way that a standardized datum referencing guideline would simplify the manufacturing process as well as reduce design complexity.

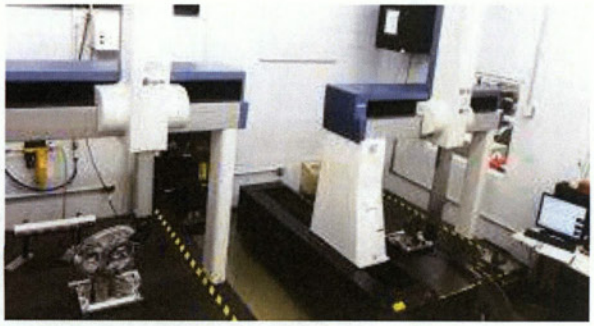


Figure 8: Coordinate Measuring Machines used for dimensional inspection

The greater, continued use of Statistical Process Control (SPC) during manufacturing

was the final area recognized by the team as an area for optimization. Before an instrument can be packaged and prepped for shipment to an OEM, it must undergo final inspection. This is done to make sure the instruments being produced meet the dimensions and CTQs given to the supplier by the OEM. The most popular tool used to determine these values is a go/no-go gage. These gages tell the user whether or not a certain dimension on an instrument is within the desired value from the OEM. The problem with go/ no-go gages is there is nothing qualitative from its use; it simply tells you if the dimension is acceptable with the given specification without giving any information pertaining to how close these values are. Because of this, there is no way to tell if machines are over or undershooting the necessary values. With SPC, the manufacturers received notice as to if the dimensions on the product meet the OEM specifications as well as numerical data on how off the product is from the expected values. This qualitative information would allow manufacturers to have greater insight into their machines' performance and correct any production imperfections earlier rather than later.

Standardization Goal & Scope

After completing the value stream for instrumentation, the next steps to accomplish our goal began with the evaluation of common instruments across knee systems. In doing this, manufacturing, quality, and regulatory requirements for instruments, as well as costs associated with varying systems were examined and compiled in a manner that lends itself best to future use for standardization.

While the thought of standardization may cause hesitation among some individuals, the team has discovered that it is not only achievable, but beneficial as well. This project will help by providing an idea of potential savings and direction to OEMs to improve their negotiating position. Based on findings throughout the project, the negotiating position for OEMs is significant because much of the savings for OEMs will depend on their negotiations with the suppliers.

Instrument Standardization Process

Along with the instrumentation value stream, the second arm of this project was to focus on opportunities for instrumentation standardization. We have chosen to present this section of information in a fashion that lends itself best to future use for standardization. A bare process will be shown on how this project progressed and how it could be used in future endeavors. We believe that this is a guideline that could apply to a wide breadth of instrumentation even covering Class II instruments. Each stage of that process will also include suggested steps to complete each stage. Specifically pertaining to our example instrument of screws, we will explain what we did in those steps to accomplish each stage. Our project's example of pins and screws will help visualize how our basic instructions from our process can be applied to different products in the future by other OrthoWorx intern teams or intra-company teams at OEMs.

Pins and Screws

Pins and screws were chosen as the target instruments of this project to use as the example within the standardization process we developed concurrently with the instrumentation value stream. Both can come in many different shapes, length, threading, and forms. For this

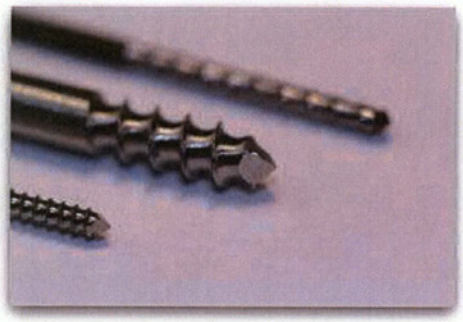


Figure 9: Threading on screws

project, we defined pins as anything needing only direct impaction to function and a screw as anything needing driven with rotation to function. Although our definition and nomenclature may be technically incorrect according to the designers of the instruments, we believe that our task was to eliminate all bias from the OEMs in terms of design and look only at functionality. This distinction provided clarity and consistency throughout the project for us when classifying pins and screws.

Selection of Instrument for Standardization

The standardization process begins with the team observing the current instrument value stream, which has been covered in the first half of this report. Once the team feels that they have an adequate understanding of the value stream, the next phase in this process is the to select an instrument for standardization. A three-step approach was used for this phase. Step one consisted of understanding the current population of instruments used in OEM knee systems. In step one, the team watched total knee arthoplasty (TKA) surgical videos to gain a base understanding of the instruments used. Then, the team reviewed publicly accessible surgical techniques for different knee systems to further out understanding of these instruments. Finally, the team participated in Sawbones skills labs and Bioskills labs to gain firsthand knowledge of these instruments and how they are used.

After a sufficient understanding of the instruments in a TKA was reached, the team moved into the second step. The goal of step two is to collect information on these instruments to build a list for instrument selection. For this step, the team looked back through the reviewed surgical techniques and recorded all of the instruments mentioned in each. Figure 10 shows the collection of instruments gathered from the surgical techniques separated into their proper section of a TKA, such as tibial preparation of femoral resection. This list not only helped the team understand what instruments are used in a TKA, but also shows how vast a collection of instruments is necessary for a total knee replacement.

With the list of instruments created, the instrument for standardization could be selected in the third step. First, the team narrowed down the list of instruments to a collection of general instruments, as seen in Figure 10. The general instruments were determined as those instruments that were found in a majority of the surgical techniques. Because of their presence in most of the surgical techniques, these instruments were also determined to be the easiest to standardize. From the general list, pins and screws or handles were the two of instruments the team narrowed down to for standardization. These instruments were chosen because they are both Class I instruments, relatively simple in design,

Figure 10: Compiled Instrument List

and offer little intrusiveness to an instrument set, meaning that the affect these instruments would have on the set is minimal. After deliberating internally and discussing with industry experts, the team selected pins and screws based on the reasons listed above as well as the lower surgeon preference to pins and screws. Surgeon preference means that a surgeon would hold a greater affinity to a handle than he or she would to a pin or screw.

Once an instrument was selected, the team determined how standardizing pins and screws would affect other instruments in the set. Figure 11 is a mind map containing the thoughts of the team in relation to pin & screw standardization. This mind map helped the team understand that just because we selected pins & screws for standardization, the affect this standardization would have on other instruments could not be neglected. For a Class II instrument, the same process described above would work, however the complexity of selecting an instrument would be increased. Specifically, handling surgeon preference would be a tougher task because surgeons have greater affinity to Class II instruments than Class I instruments.

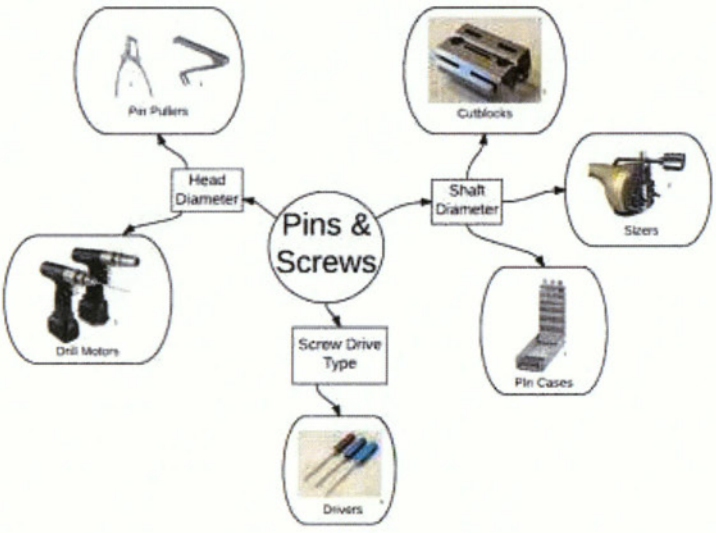


Figure 11: Instrument Mind Map

Business Risks, Dependencies, and Mitigations

Business Risks

Potential risks that could affect the standardization of instruments include intellectual property (IP) inertia, FDA classification of the instrument(s) in question, and new development/predicate introduction of standardization. One of the main risks when attempting to achieve change in any instance is inertia; that is, the resistance to change. It typically takes determination and the acceptance of one mission or goal, among all parties, to overcome this hurdle, but it is necessary to succeed at standardization. The group was able to negate much of the aforementioned inertia by signing non-disclosure agreements (NDAs) with all OEMs and suppliers with whom we dealt. This allowed our team to ask questions that might otherwise cause concern in regard to the information requested.

The freedom to exchange information under these agreements would eventually lead to the ability to perform quantitative analysis based on real data in order to provide legitimate recommendations. Another risk that companies may encounter is a higher classification of instrument. Class I instruments can be standardized with little to no FDA involvement, but as the class increases, more involvement is required by regulatory in order to comply with FDA guidelines.

Furthermore, the intended application of a standardized instrument is important to understand. If the instrument is going to be implemented immediately, it would require a recall of current instruments in the field, which would most likely cost the OEMs more than the savings from standardization, especially if the standardization of one instrument (such as a screw

in this case) affects numerous other instruments that are critical to the functionality of the standardized instrument. Inversely, if the standardized instrument is treated as a new development, then the companies can introduce the instrument in a future system, only affecting the use of old instruments with new surgeries that are performed.

Dependencies

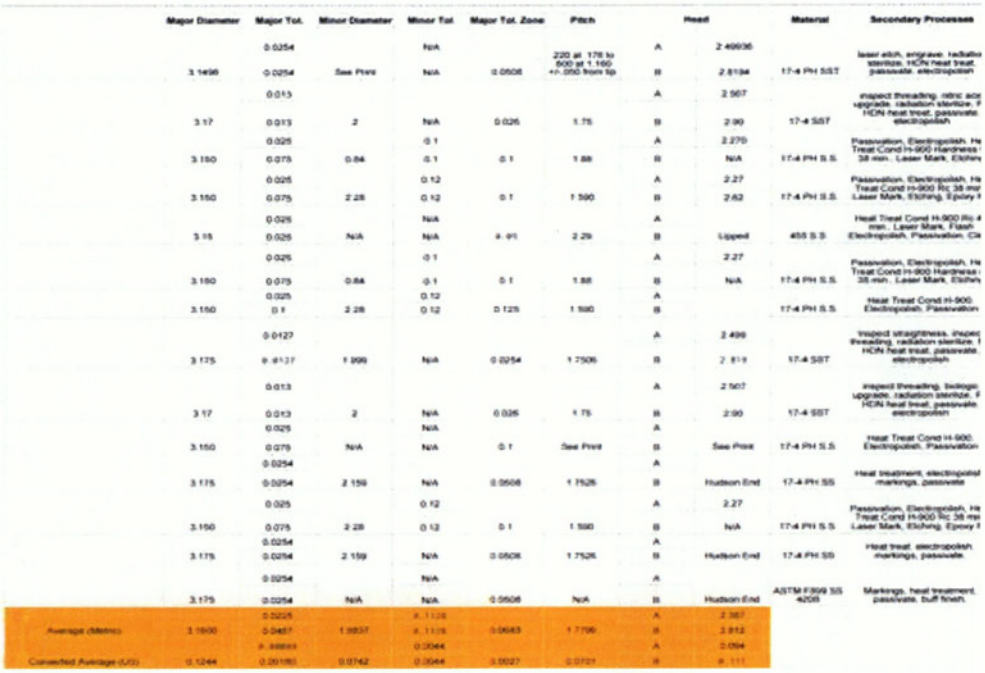
Some dependencies identified that can determine the success of standardization projects are time constraints, access to information, and the capacity to decipher varying information from different OEMs. While time constraints may vary within and between companies, as an internship, the project performed during this summer of 2016 was restricted to only ten weeks. This shows that, while standardization is not simple, it can be systematically approached and is an achievable process.

Additionally, limited access to information could be a challenge faced when trying to gather data. As a team, the interns learned that the most efficient way to move forward with the project was to overlap information gathering with analysis, which enabled the team to run as much congruent analysis as possible, minimizing the down-time between fluxes in data collection.

After mitigation of time constraints and access to information, the next step was to analyze the data that was received. This was a major issue throughout the project because often there would be spreadsheets or other information sources that were unclear due to their native labeling methods and/or nomenclature. The main setback from this is that it caused more time to be spent in hiatus trying to decipher and waiting on guidance of the significance within the documents.

Data Analysis

The analysis of pins and screws began at a very rudimentary level of examining online, publicly available surgical techniques that are provided by OEMs for surgical education pertaining to an orthopedic implant system, which includes the implants and instruments. These surgical techniques provided foundational education on implant systems and how they operate early in the project as well as gave us an understanding of the role and importance of instrumentation in a system. Depending on the surgical technique, the part numbers of instruments used in the surgery were also provided along with the name and its use. From this information provided by the brochures, the team had compiled a list of every instrument listed in the surgical techniques of seven orthopedic total knee replacement systems giving good groundwork to begin analyzing the most common instruments by quantity present in cases and by surgical use.



Major Diameter	Major Tol.	Minor Diameter	Minor Tol.	Major Tol. Zone	Pitch		Head	Material	Secondary Processes
	0.0254		N/A			A	2.49936		
3.1496	0.0254	See Print	N/A	0.0508	220 at .176 to 500 at 1.160 +/-.050 from tip	B	2.8194	17-4 PH SST	laser etch, engrave, radiation sterilize, HCN heat treat, passivate, electropolish
	0.013					A	2.567		
3.17	0.013	2	N/A	0.025	1.75	B	2.90	17-4 SST	inspect threading, nitric acid upgrade, radiation sterilize, HCN heat treat, passivate, electropolish
	0.025		0.1			A	2.270		
3.150	0.075	0.84	0.1	0.1	1.88	B	N/A	17-4 PH S.S.	Passivation, Electropolish, Heat Treat Cond H-900 Hardness 38 min., Laser Mark, Etching
	0.025		0.12			A	2.27		
3.150	0.075	2.28	0.12	0.1	1.590	B	2.62	17-4 PH S.S.	Passivation, Electropolish, Heat Treat Cond H-900 Rc 38 min., Laser Mark, Etching, Epoxy
	0.025		N/A			A			
3.15	0.025	N/A	N/A	4.91	2.29	B	Lipped	455 S.S.	Heat Treat Cond H-900 Rc 4 min., Laser Mark, Flash Electropolish, Passivation, Cle
	0.025		0.1			A	2.27		
3.150	0.075	0.84	0.1	0.1	1.88	B	N/A	17-4 PH S.S.	Passivation, Electropolish, Heat Treat Cond H-900 Hardness 38 min., Laser Mark, Etching
	0.025		0.12			A			
3.150	0.1	2.28	0.12	0.125	1.590	B		17-4 PH S.S.	Heat Treat Cond H-900, Electropolish, Passivation
	0.0127					A	2.499		
3.175	0.0127	1.999	N/A	0.0254	1.7526	B	2.819	17-4 SST	inspect straightness, inspect threading, radiation sterilize, HCN heat treat, passivate, electropolish
	0.013					A	2.567		
3.17	0.013	2	N/A	0.025	1.75	B	2.90	17-4 SST	inspect threading, burrings, upgrade, radiation sterilize, HCN heat treat, passivate, electropolish
	0.025		N/A			A			
3.150	0.075	N/A	N/A	0.1	See Print	B	See Print	17-4 PH S.S.	Heat Treat Cond H-900, Electropolish, Passivation
	0.0254					A			
3.175	0.0254	2.159	N/A	0.0508	1.7526	B	Hudson End	17-4 PH SS	Heat treatment, electropolish markings, passivate
	0.025		0.12			A	2.27		
3.150	0.075	2.28	0.12	0.1	1.590	B	N/A	17-4 PH S.S.	Passivation, Electropolish, Heat Treat Cond H-900 Rc 38 min., Laser Mark, Etching, Epoxy
	0.0254					A			
3.175	0.0254	2.159	N/A	0.0508	1.7526	B	Hudson End	17-4 PH SS	Heat treat, electropolish, markings, passivate
	0.0254		N/A			A			
3.175	0.0254	N/A	N/A	0.0508	N/A	B	Hudson End	ASTM F899 SS 4205	Markings, heat treatment, passivate, buff finish
	0.0225		0.1125			A	2.367		
Average (Metric)	3.1600	0.0457	1.9837	0.1125	0.0563	1.7700	B	2.813	
	0.00889		0.0044			A	0.004		
Converted Average (US)	0.1244	0.00180	0.0742	0.0044	0.0022	0.0701	B	0.111	

Figure 12: Sterilized Screw List

Numerical data gathering began with prints and control charts from OEMs and suppliers. These were used to study dimensioning, tolerancing, and comparing secondary processes listed in the notes. Data sheets were created for both pins and screw and populated with the information from the prints and control charts and all figures became standardized into metric. This allowed the team to very clearly understand the differences between instrumentation for OEMs. The amount of prints gathered from the OEMs and suppliers involved provided totaled four pins and fifteen screws. Our focus directed solely toward treaded screws due to this skew of data availability.

Standard Screw

Our standard screw analysis began with our list of screws compiled from the prints we received from OEMs. We examined the list and chose one representative screw from each OEM giving us three screws for our experiment. The selection of the screws was based off of having the most variability present in each screw compared to the average calculated from the list of screws. Inversely, the representative screw could not be too much of an outlier so we also took into account that it needed to remain as close as possible to the calculated average. This balance of variability and consistency compared to the industry average we had was decided based off team debates in an effort to gain the most information about manufacturing costs from different features. An assumption had to be made that all three screws held the same functional capabilities to eliminate any additional variables that would have pushed this experiment outside of our available timeframe. We then spoke to industry experts who confirmed our procedure and assumptions. The experiment was then sent to a supplier who ran cost estimates on each screw. The costs were broken down into machining time per operation and any additional costs needed

like unique features and secondary operations. After receiving these results, our team was able to produce a control screw compare against.

The control screw we compiled was assembled from the most time-efficient feature available in the three screws. This gave us the fastest screw production possible using the features already included by the industry. The largest factors in machining time were features like the threading, fluting, length, and drive of the screws and the more unique features on the screw also created additional machining time from the tool change between features. The fewer machining operations that can be performed per screw the less time is wasted with tooling changes and its associated cost. Also, any tolerances in the magnitude of ten thousandths increase cost due to be so tight. Machining time and cost were found to be correlated to .992 so we assumed for our model that we could use this as perfectly correlated for our calculations.

Cost Model

After we shortlisted the 3 screws that we chose to standardize, we explored ways of analyzing the benefits accrued from standardizing, and zeroed in on process time and cost as the 2 variables for measuring the same benefits. With inputs from industry practitioners, we estimated standard process times and costs at a hypothetic volume for each of the 3 screws, and the same for the standard screw at the combined volume.

Our efforts revealed that the standardized screw took less manufacturing time per unit by 25%, and attracted lower manufacturing cost per unit by 12% compared to each of the input screws. We are not at liberty to divulge the inputs that went into our analysis due to IP and our signed agreements. However, the potential of saving 25% in process time and 12% in costs itself should warrant independent evaluations within an OEM or across the industry. There are other areas of the entire supply chain where a company is likely to record savings, right from procurement to logistics and distribution,

- Higher economies of scale in procuring raw materials (especially if the material of construction is standardized along with the design)
- Greater manufacturing efficiency because of:
    - Fewer changeovers in production
    - Reduced downtime (arising out of fewer changeovers)
    - Lower scrap rates (better standardization of processes to suit the product)
    - Lower obsolescence rates (especially caused by return of predicate instruments and rollouts of new instruments)
    - Lower labor costs (greater scope for mechanization)
- Better forecast accuracy and inventory management because of fewer stock-keeping units (SKUs) – forecast inaccuracies reduce exponentially as product-portfolios get consolidated with fewer SKUs
- Better cash management – less capital is blocked in manufacturing and instrument inventory
- More efficient operations at the distributor, especially in case-assembly time

Our underlying purpose in this presentation has been to explore the applicability and benefits of standardizing instruments. Earlier in our presentation, we identified the instruments that could potentially be standardized. We have used 'pins and screws' to illustrate a process. Even if an OEM was to focus only on a pin, they would need to standardize pin-pullers, cut-blocks, and drill-bits. The same OEM will realize tangible and intangible efficiencies from standardizing these instruments too, which will lead to streamlined operations, simpler processes, easier supervision, and hence greater financial gain.

Even if it's early days for the industry to come together to standardize a pin across OEMs, there is merit in evaluating pin- and screw-standardization across different joint systems or even only their knee-implant systems.

References

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Appendix

Acronyms

ASTM: International standards organization that publishes technical standards for materials, products, systems, and services
CAD - Computer-Aided Design: Modelling program used for product design
CMM - Coordinate Measuring Machine: automated dimensional inspection machine used heavily for quality control
CNC - Computer Numerical Control: Computer-automated machine used for manufacturing purposes
CTQs - Critical to Quality "Features": dimensions, tolerances, or notes that are defined as critical to the product's performance
DFM - Design for Manufacturing: Product design with intent for the simplest production possible
DHF - Device History File: File containing all process validation, verification, and rationale
DMR - Device Master Record: All instructions, prints, models, and other documents needed to manufacture a product
FDA - Food & Drug Administration: United States Federal agency presiding over consumer goods
ISO - International Organization for Standardization: International standards organization composed of representatives from various national standards organizations
IP - Intellectual Property: Anything considered confidential by a company
MRI - Magnetic Resonance Imaging: Detailed internal body imaging test using a magnetic field and radio waves
NDA - Non-Disclosure Agreement: Legal document preventing sharing of confidential information beyond those in agreement
NRE - Non-Recurring Engineering: Any single-time costs from a supplier to OEM for sample runs
OEM - Original Equipment Manufacturer: designer and owner of product such as DePuy Synthes, Medtronic, OrthoPediatrics, or Zimmer Biomet
OR - Operating Room: Hospital room for surgeries
PMA - Premarket Approval: FDA review process to evaluate a product which requires adequate evidence that it is safe and effective
RFQ - Request for Quotation: Supplier estimates the costs to fulfill and OEM's order
RTA - Refusal to Accept: FDA notification requiring more information about something in a Submission before it can receive clearance
SKU - Stock Keeping Unit: product code, usually a barcode, used for inventory management
SPC - Statistical Process Control: dimensional inspection that uses quantifiable data to track manufacturing processes
TKA - Total Knee Arthroplasty: total knee joint replacement

Definitions

510(k) Submission - Submission proving predicate equivalence that is required to gain Pre-Market Notification
(PMN)
Bioskills Lab - Cadaver lab housed at Paragon Medical
C-Suite - Corporation's most important senior executives
Class I Instrument - Noninvasive, low risk instruments that can be used across systems.
Class II Instrument - Instrument are more specific and provide more risk in a surgical
Drive Type - Connection between the screw and driver; a hex or Phillips head would be layman examples
Instrument - Any product assisting in orthopedic surgery
Fluting - Cutting grooves present on drill bits
Sawbones Lab - Artificial, foam cadaver lab housed at Zimmer Biomet
Supplier - Manufacturing company responsible for machining products for OEMs such as Paragon